RECEIVED
CENTRAL FAX CENTER
JUL 12 2004

OFFICIAL

RLL-124CIPUS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: RAMPAL *et al.*

Examiner: LUKTON, David

Application No.: 09/973,265

Group Art Unit: 1653

Filing Date: October 9, 2001

Title: A STABLE ORAL PHARMACEUTICAL COMPOSITION CONTAINING OMEPRAZOLE

Certificate of Facsimile Transmission

I certify that this correspondence, consisting of 8 pages, is being sent via facsimile transmission to (703) 872-9306 to Technology Group 1653 of the United States Patent and Trademark Office on July 12, 2004.

William D. Hare

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

RESPONSE TO RESTRICTION REQUIREMENT MAILED JUNE 10, 2004

Initially the Applicants' representative wishes to thank the Examiner for his helpful comments regarding the restriction/election requirement mailed June 10, 2004. His comments have been used in preparing this response

In the restriction requirement, the claims are subject to restriction between Group 1 (claims 1-29, drawn to a composition), Group 2 (claims 1-23, drawn to a composition), Group 3 (claims 1-20, drawn to a composition), Group 4 (claims 30-37, 42, 43, 46, and 47, drawn to a method of making a composition), Group 5 (claims 30-37, 42, 43, 46, and 47, drawn to a method

of making a composition), and Group 6 (claims 30-42, 46, and 47, drawn to a method of making a composition). Applicants elect the claims of Group 1.

The claims are further subject to an election of species requirement. As discussed with the Examiner, the election of species requirement is to be based on the compositions disclosed in the application. As such, Applicants elect the species of the composition of Example 8, which is disclosed in Tables 2 and 11. Table 2 discloses an illustrative enteric coating comprising Eudragit L-100-55, sodium hydroxide, titanium dioxide, talc, and polyethylene glycol-300. Table 11 discloses a capsule formulation comprising nonpareil seeds, a seal coat, active layer, intermediate layer, and enteric layer. The seal coat comprises cross-linked polyvinylpyrrolidone (PVP), PVP K30, talc, and polyethylene glycol. The active layer comprises cross-linked PVP, PVP K30, Talc, and omeprazole. The intermediate layer comprises sugar and cross-linked PVP. The enteric layer comprises Eudragit L-100-55 and can be used to coat pellets that are filled into a capsule.

Applicants submit that claims 1-7, 9-14, 16, 17, 19, and 21-29 are included within this species. With respect to claims 2 and 3, the seal coat and active layer both include cross-linked PVP. With respect to claims 4 and 5, PVP is a water soluble polymer. With respect to claim 6, omeprazole makes up over 40% by weight of the active layer. With respect to claims 7 and 9-11, the seal coat and active layer include talc (a lubricant excipient) and the seal coat includes polyethylene glycol (a plasticizer excipient). With respect to claims 12 and 13, the composition includes PVP (a binder) and mannitol (a filler), respectively. With respect to claims 14 and 17, the composition includes an enteric layer or coating made from an enteric material, Eudragit L-100-55. With respect to claims 16 and 19, the composition of this example was filled into a capsule in the form of granules, which are comparable to pellets in this application. With respect to claims 21 and 22, the composition includes a seal coat that coats a neutral core. With respect to claim 23, the seal coat includes polyethylene glycol and PVP K30. With respect to claim 24, the composition further includes an intermediate layer and an enteric layer. With respect to claim 25, the enteric layer includes an enteric polymer, Eudragit L-100-55. With respect to claim 26, the intermediate layer includes cross-linked PVP and sugar. With respect to claim 27,

the composition of Table 11 includes a neutral core coated with a mixture of omeprazole and a pharmaceutically acceptable carrier, one or more intermediate layers, and an enteric coated layer. With respect to claims 28 and 29, the composition is in the form of pellets or beads (i.e., granules) that are filled into a capsule.

In summary, Applicants select Group 1 (claims 1-29) for examination subject to the election of species of the composition of the embodiment of Table 11 (claims 1-7, 9-14, 16, 17, 19, and 21-29).